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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,591	07/10/2000	William J. Boyle	A-378CIP5	9711

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/613,591	BOYLE ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-25,39-42 and 62-66* is/are pending in the application.

4a) Of the above claim(s) *65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-25,39-42,62-64 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05 April 2004 has been entered.

Status of Application, Amendments and/or Claims

The amendment filed 05 April 2004 has been entered in part. Claims 1-16, 26-38, 43-61 are cancelled. Claim 17-25, 39-42, 62-66 are pending.

Claim 65 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 65 recites, "wherein the OPG protein comprises an antibody to OPG ligand". Applicant elected Group IV, claims drawn to a method for treating conditions leading to bone loss which comprises administering isolated OPG protein, IL-1 inhibitor and TNF-α inhibitor. Please see Election/Restriction 22 March 2002, Paper No. 24. Claim 65 adds a new limitation (antibody to OPG ligand).

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 65 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 17-25, 39-42, 62-64 and 66 are under examination.

Claim Objections

Claims 17, 19, 24 and 66 are objected to because of the following informalities:

Claim 17 encompasses a non-elected invention and requires amendment to limit to elected invention. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 19 is objected to because of the recitation of "TNF-••inhibitor" instead of "TNF-α inhibitor".

Claims 24 and 66 are objected to because the instant claims appear to read on the same scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-25, 39-42, 62-64 and 66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method of **treating bone loss**, which comprises administering an IL-1 inhibitor, a TNF-α inhibitor and an OPG protein, wherein OPG protein refers to a polypeptide

comprising conserved residues from residues 22 to 185 of SEQ ID NOs: 121, 123 and 125,

does not reasonably provide enablement for:

a method of **treating a condition resulting in bone loss**, which comprises administering an IL-1 inhibitor, a TNF-α inhibitor and an OPG protein, wherein OPG protein refers to a polypeptide comprising conserved residues from residues 22 to 185 of SEQ ID NOs: 121, 123 and 125.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches the SEQ ID Nos for rat, mouse and human OPG protein. The specification states that amino acid residues 22-185 define a region of OPG activity (page 154, lines 14-17). The specification teaches a combination treatment of OPG-Fc (22-194) and sTNFR-I or OPG-Fc (22-194) and IL-Ira on bone density loss in adjuvant arthritis using rat models (Figures 31A, 31B and Example 14). Loss of bone mineral density was measured. The combination treatment decreased bone density loss. However, while conditions such as rheumatoid arthritis, multiple sclerosis, osteoporosis and osteomyelitis may share the common pathology of excessive bone loss, there are many other elements which characterize these conditions that are vastly different. For instance, multiple sclerosis (neurodegenerative disease) would have a very different etiology and treatment compared to rheumatoid arthritis (chronic inflammatory disease). The instant claims read on treating the condition, however based

on the working examples in the specification, the instant method is actually treating the bone loss. The specification fails to teach that these diverse conditions are being treated upon administered OPG and sTNFR-I or IL-Ira (i.e. use of art recognized animal models). The specification fails to teach any parameters that would help one skilled in the art discern if a condition resulting in bone loss in a subject is responding to OPG/sTNFR-I or IL-Ira treatment. The scope of the instant claims exceeds the scope of the enabling disclosure.

Due to the large quantity of experimentation necessary to treat a condition resulting in bone loss comprising administering OPG and IL-1 inhibitor or TNF-α inhibitor, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, and the breadth of the claims which fail to recite limitations regarding treatments, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
6/8/04

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER